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| 10/517,592 | 08/15/2005 | Morten Sloth Weidner | 030307-0249 | 1815 |
| 23428 7590 07/09/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | | |
| | | | EXAMINER KAROL, JODY LYNN | |
| | | | ART UNIT 1617 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary

Application No.

10/517,592

Applicant(s)

WEIDNER, MORTEN SLOTH

Examiner

Jody L. Karol

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/17/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64, 66, 67 and 69-92 is/are pending in the application.
- 4a) Of the above claim(s) 77-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64, 66-67, and 69-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/08)
Paper No(s)/Mail Date 12/13/2004 and 9/8/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to the Response to the Restriction/Election and amendments filed 4/17/2008. Claims 63, 65 and 68 have been cancelled. Claims 64, 66-67, and 69-92 are pending.

Election/Restrictions

1. Applicant's election **with** traverse of Group I, claims 63-76 directed to a composition comprising a combination of (i) a fatty acid ester of formula I or isomer thereof and (ii) niacinamide, a salt, or derivative thereof and species election **with** traverse of (a) 1-glycerol monocaprylate, (b) niacinamide, and (e) topical administration in the reply filed on 4/17/2008 is acknowledged.

The traversal is on the ground(s) that the claims have been amended to obviate the evidence that the common technical feature among the groups, a composition comprising a fatty acid ester of formula I and niacinamide, a salt, or derivative thereof, is known in the prior art as taught in De Ritter et al. (US 3,676,556). This is not found persuasive because the determination of whether or not any particular feature makes a "contribution" over the prior art and therefore constitutes a "special technical feature" is considered with respect to novelty and inventive step. Applicants assert that in the present claim set R' no longer encompasses fatty acids of C₁₆-C₁₈ chain length, which eliminates the fatty acids taught by De Ritter et al. In the present claim set R' is a C₆-C₁₄ alkyl group, which encompasses C₇-C₁₅ alkyl groups. Modifying the chain length of the fatty acid ester by one carbon is considered to be an obvious modification to one of

ordinary skill in the art, and thus an inventive step is lacking. Accordingly, the unity of invention is still considered to be lacking, and the restriction in accordance with the rules of unity of invention is still deemed proper.

In regards to the species election, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 77-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 63, 65 and 68 have been cancelled. Accordingly, claims 64, 66-67, and 69-76 are examined on the merits herein. Prior art will be applied to the claims in so much as it reads on the elected species.

Priority

2. This Application is a 371 of PC/DK03/00423 International Filing Date: 6/20/2003, which claims foreign priority to Application No. PA 2002 00951 filed in Denmark on 6/20/2002 and domestic priority to Provisional Application No. 60/389879 filed on 6/20/2002.

Information Disclosure Statement

3. The information disclosure statements (IDS) filed on 12/21/2004 and 9/8/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered. However, several of the documents have

not been considered because English language translations of the documents were not provided or readily available, and their relevance to the application has not been indicated.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 71 recites the broad recitation "in a molar ratio of between about 1:10000 to 10000:1," and the claim also recites "preferably about 1:1000 to 1000:1, more preferably of about 1:100 to 100:1, even more preferably of about 1:10 to 10:1, most preferably of about 1:5 to 5:1 or about 1:2 to 2:1" which is the narrower statement of the range/limitation.

For examination purposes, and in the interest of compact prosecution, the molar ratio of components in claim 71 will be interpreted as between about 1:10,000 to 10,000:1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

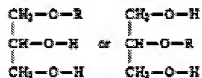
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 64, 66-67, and 69-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Traupe et al. (US 5,759,584) in view of Shalita et al. ("Topical

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Nicotinamide Compared with Clindamycin Gel in the Treatment of Inflammatory Acne Vulgaris" *Int. J. Derm.*, Vol. 4, No. 6, June 1995, pgs 434-437).

The instant claims are directed to composition comprising a combination of 1-glyceryl monocaprylate and niacinamide. It is noted that niacinamide is also known as nicotinamide (see page 3, line 5 of the instant specification).

Traupe et al. teach the use of a composition comprising distilled wool wax acids and at least one monoglycerol monocarboxylic acid monoester, or formulations comprising such active compound combinations for the treatment of blemished skin, mild forms of acne, and *Propionibacterium acnes* (see abstract and column 1, lines 29-41). Traupe et al. further teach that the monoglycerol monocarboxylic acid monoesters are represented by the general formula:



wherein R is particularly advantageously the octanoyl radical (caprylic acid radical), and in a preferred embodiment is glycerol monocaprylate (see column 3, lines 16-50 and column 4, lines 29-36). The glycerol ester esterified at the 1-position of glycerol (i.e. 1-glycerol monocaprylate) has a centre of asymmetry, wherein the 2S and 2R configurations are both active, and racemic mixtures of the stereoisomers is favorable as claimed in the instant claim 72 (see column 3, lines 48-56). Traupe et al. further teach that the formulations which are active against blemished skin can be in the form of face lotions, etc. indicating they include cosmetics formulated for topical administration (see column 4, line 55 to column 5, line 12).

Traupe et al. do not teach compositions additionally comprising niacinamide.

Shalita et al. teach 4% nicotinamide (niacinamide) gel is comparable in efficacy to 1% clindamycin gel in the treatment of acne vulgaris (see abstract). Shalita et al. further teach that the nicotinamide gel is a desirable alternative treatment for acne vulgaris because antimicrobials such as clindamycin are associated with resistant microorganism such as *Propionibacterium* (see abstract and page 434, and Discussion on pages 436-437).

It would have been obvious to one of ordinary in the art at the time of the invention to combine the wool wax and acid and glycerol monocaprylate composition taught by Traupe et al. with the nicotinamide composition taught by Shalita et al. One of ordinary skill in the art would have been motivated to so because both compositions are useful for treating acne. One of ordinary skill in the art would have a reasonable expectation of success because both compositions are taught to target a specific cause of acne, namely *Propionibacterium*. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, it would be obvious to one of ordinary skill in the art at the time of the invention to optimize the ratio of 1-glycerol monocaprylate to niacinamide as claimed in the instant claim 71. Proportions of ingredients, to impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. *In re Fields* (CCPA 162) 304 F2d 691,134 USPQ 424.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weidner (US 6,087,391) teaches rendering organic compounds comprising a hydrophilic group soluble in fatty systems, by forming a complex with a fatty acid ester of a polyhydroxyalkane (i.e. glycerol monocaprylate).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/San-ming Hui/
Primary Examiner, Art Unit 1617